

# European Network of GMO Laboratories

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## ACTIVITY REPORT

2002-2004



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL  
**Joint Research Centre**





# European Network of GMO Laboratories

ACTIVITY REPORT

## **Abstract**

The activity report of the European Network of GMO Laboratories describes the progress made and the work carried out from the official inauguration of the Network held in Brussels, Belgium, on 4<sup>th</sup> December 2002 to nowadays. It provides a general overview of the scientific activities, accomplishments and resources related to this expert group (in 2004 more than 70 European laboratories are included in the Network under the chairmanship of the JRC-Biotechnology & GMOs Unit) that has been set up to create a forum for EU and EEA to collaborate on detection and quantification of GMOs, on sampling and on the development of suitable reference materials.

An overview is given of the mission and its implementation, the relations with the outside world and a particular emphasis is given to the personal experience of participating experts.

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# Foreword from European Research Commissioner



As Research Commissioner, I have always given high priority to the field of GMOs and their implications on human and animal health, the environment and the industrial sector. The promotion of dialogue between research and society and the preparation and implementation of an EU regulatory framework play key roles in EU policy making on this topical issue.

Networking plays a pivotal role in the European Research Area and the European Network of GMO Laboratories (ENGL), with 71 members, is a prime example of a real success story. The Joint Research Centre played a catalytic role in the establishment of ENGL and during my inaugural speech on 4 December 2002, I drew attention towards the need to ascertain a stringent EU regulatory framework for GMOs. Despite the different thresholds for various commodities and fields of application that such a framework requires, compliance with complex regulations is now being achieved thanks mostly to this network of top scientists that develop, improve and validate control methods. It is not surprising that, only months after its inauguration, the European Network has not only grown in size but it has built up a reputation of excellence that is being acknowledged by the services of the European Commission and EU industries and trade partners.

The rather recent nomination of the Joint Research Centre, together with ENGL, as Community Reference Laboratory again signifies scientific excellence. This is exemplified through its pioneering work on sampling, certified reference materials, method development and validation and, of course, not forgetting its proactive role in training young scientists and technicians.

I acknowledge the achievements of ENGL and the Joint Research Centre and I wish its members continued success during the coming years. I am convinced that this work provides, and will continue to provide, the backbone for guiding and implementing European Union policies on GMOs.

**Philippe Busquin**

European Research Commissioner



*ENGL inauguration ceremony on 4<sup>th</sup> December 2002 in the presence of European Research Commissioner Philippe Busquin*



## Message from Director General JRC



In its function as the EU's research-based policy support organisation, the Joint Research Centre (JRC) attaches great importance to underpinning the GMO regulatory framework. This may be exemplified through:

- The production of the first certified reference materials for GMO tests at the JRC's Institute for Reference Materials and Measurement (IRMM) in Belgium;
- The prospective study of co-existence between traditional, organic and GM crops at the JRC's Institute for Prospective Technology (IPTS) in Spain;
- The development, optimisation and validation of analytical methods to comply with GMO regulations at the JRC's Institute for Health and Consumer Protection (IHCP) in Italy.

When member states' experts met at the JRC in 1999 to discuss the scientific difficulties and challenges they faced in complying with GMO regulatory requirements, I was aware of the potential strength of this expert group. So with the backup of Commissioners Busquin and Byrne, I gave my full support to the further development of what later became known as the European Network of GMO Laboratories (ENGL).

When reading this ENGL activity report, I see that this work reflects the priorities of the JRC. For example, the nomination of the JRC as Community Reference Laboratory for the GM Food and Feed Regulation will have far-reaching implications, not only for the JRC and the European Commission, but for the Union as a whole. ENGL has lined up with the rest of the JRC in placing enormous importance on Enlargement: the addition of 24 laboratories from the New Member States is highly significant. Also, important advances have been made on research projects and these in turn have already shown their impact on the regulatory framework and on European Standardisation. In this respect, I wish to highlight the production of certified reference materials, the search for alternatives (e.g. plasmids) and the excellent work on sampling. This work has contributed enormously to legislation on traceability and labelling and is now in the process of becoming an EU standard.

I am confident that ENGL will continue to impress all stakeholders with its cocktail of expertise, innovation and excellence and I am convinced that this will foster the development of such networks in other areas. I congratulate the JRC staff and all members of the ENGL and I wish them all the best in their future work.

**Barry Mc Sweeney**  
Director General JRC



*ENGL inauguration ceremony on 4<sup>th</sup> December 2002. Director General JRC Barry McSweeney signs the agreement on behalf of the European Commission-Joint Research Centre*





# The European Network of GMO Laboratories



It is the intention of the Commissions to develop a competitive European biotechnology community based on the establishment of a strict regulatory framework on the one hand, and on building transparency and public confidence on the other. Over the last few years a number of regulations have been developed that include, for instance, strict labelling requirements for products that contain living GMOs or their derivatives. It has turned out that biotechnology companies, as well as control authorities, trade partners as well as importers have struggled for many years with the analytical implications of such regulations. Now, with the installation of a strong pan-European network of scientists, many of those technical issues may be tackled making the regulatory framework more operational.

In the late nineties, control laboratories throughout Europe have together initiated discussions and have, under the chairmanship of the European Commissions' Joint Research Centre, made an inventory of all technical difficulties that need to be solved in order to be able to meet the expectations from the consumers, as well as from the biotech producers to establish a transparent and watertight control system. Today, more than 70 EU control laboratories have joined the "European Network of GMO laboratories" to work together on harmonized and efficient methods for sampling, on development of reliable methods for the detection, identification and quantification of GMOs, as well as on the production of reference materials.

The major activities of ENGL deal with:

- Method development and optimisation, subsequently followed by international validation;
- Proposal of strategies for sampling bulk quantities of seeds, grains, ingredients and food and feed products for presence of low amounts of GMO's;
- Development of appropriate reference samples to be included in analytical tests;
- Exchange of data obtained with control activities;
- Develop a molecular database that contains all the sequences of approved and non-EU approved GMOs with the appropriate interrogation tools.

Members of the ENGL are appointed by EU National Competent Authorities who are responsible for GM seeds, GM food and GM feed. Norway and Switzerland are also officially involved.

ENGL is chaired by the Institute for Health and Consumer Protection of the Joint Research Centre. As the chairman I am assisted by a Steering Committee that consists of one representative per Member State. Decisions are made by consensus.

As a rule of the thumb, two Plenary Sessions and two Steering Committee sessions are held per year, and a number of working group meetings are convened as required.

From the scientific viewpoint, I have had the privilege to be assisted by a team of excellent experts who have prepared outstanding data for each meeting on a variety of complex issues. Also the members of ENGL itself, as well as participating colleagues from other Commission services, have always contributed actively so that each meeting was of an outstanding technical level.

The effort required for managing these meetings is also considerable. Particularly off-site meetings such as in Varna (Bulgaria) or Prague (Czech Republic) were very challenging to organize, but my staff did in all cases an excellent job.

This document will show that ENGL is a coherent structure of top-class researchers who appreciate working together and who are assisted by an excellent administrative support team.

I give my thanks to all,

**Guy Van den Eede**

Chairman ENGL  
Head of Unit, Biotechnology and GMOs

## From ENGL to CRL



<http://engl.jrc.it>

The level of expertise and the international profile of the ENGL have been acknowledged by the European Commission, and in particular by DG SANCO, by appointing the JRC — in collaboration with ENGL — as the Community Reference Laboratory (CRL) in the context of Regulation (EC) 1829/2003 on GM food and feed. This CRL nomination is a “JRC first”. Its tasks include:

- reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples,
- testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed,

- evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,
- submitting full evaluation reports to the European Food Safety Authority (EFSA).

The Community Reference Laboratory shall also play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

Further guidance to the operation of the CRL can be found in “Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003”, which has been co-drafted by the JRC and DG SANCO.

In November 2003 the ENGL Plenary Meeting finalised the document “Definition of minimum performance requirements for analytical methods of GMO testing”. This document provides information about the method validation process and its requirements with respect to the regulatory compliance and control purposes. In 2004, with the support of four experts of ENGL, detailed procedures have been laid down for the operation of the CRL. Since April – as requested by the Community Legislation – the CRL is fully operational.

For more information: <http://gmo-crl.jrc.it>



<http://gmo-crl.jrc.it>

# Support to the Enlargement Action

Over the last few years, the Joint Research Centre has undertaken substantial efforts to integrate Enlargement countries' experts and organisations in its activities and projects.

The JRC Enlargement Action consists of a number of integrated activities aimed at stimulating collaboration within research projects, hosting temporary staff at the JRC premises, organising workshops and training courses, and disseminating information and enhancing communication with the Enlargement Countries.

The objective of the JRC Enlargement Action is to support the EU Enlargement policy and contribute to the widening of the European Research Area. It deals, in particular, with complex scientific and technical aspects underpinning EU legislation that are presently handed by the JRC. It covers a wide range of areas, such as environment, health, food, renewable energy, chemicals, agriculture and nuclear safety. Most activities are carried out in close co-operation with the relevant policy DGs.

The JRC Enlargement Action resulted in training 1200 experts in 2002, hosting 80 researchers at the JRC institutes (August 2003) and establishing some 300 new partnerships with scientific and technical organisations in the Enlargement Countries.

The JRC can play a catalyst role in the continuous integration of AC/CC in the European Research Area. Notably the JRC can via joint submissions for FP6 projects, in which it acts as partner at equal footing, promote the participation of CCs in integrated projects and other FP6 instruments. Since January 1st 2003, the JRC has been involved in 160 research proposals submitted to various FP6 calls. Over 70% of these proposals include one or more partner(s) from Enlargement country(ies).

**Giancarlo Caratti**

Head of the JRC Enlargement Unit

On April 29<sup>th</sup> 2004 in Prague (CZ) the ENGL welcomed 24 laboratories from Accession Countries and as such aligned well with the process of Enlargement. With this, the total number of members has reached 71 laboratories, and the Steering Committee has 26 permanent members.



*Stakeholders' conference and inauguration ceremony held in Prague on 29<sup>th</sup> April 2004*



*The ENGL chairman with representatives of the 24 GMO laboratories from Accession Countries who officially signed the ENGL agreement*



*Press conference with two of the czech ENGL representatives*



## ENGL Steering Committee



**Guy Van den Eede**  
Chairman



**Yves Bertheau**  
INRA PMDV DMO / FR



**Patricia Bonner**  
State Laboratory / IR



**Hermann Broll**  
Bundesinstitut für  
Risikoewertung (BfR) / D



**Anna Christodoulidou**  
General Chemical  
State Laboratory / GR



**Andrew Damant**  
Food Standard Agency / UK



**Eugenia De Andrade Silva**  
Direcção-Geral de Protecção  
das Culturas / PO



**Andreas Heissenberger**  
Umweltbundesamt (UBA) / A



**Rupert Hochegger**  
Austrian Agency for Health  
and Food Safety (AGES) / A



**Arne Holst-Jensen**  
National Veterinary Institute / NO



**Marina Miraglia**  
Istituto Superiore di Sanità  
(ISS) / IT



**William Moens**  
Institute of Public Health / B



**Emile Laurensse**  
The Food and Consumer Product  
Safety Authority / NL



**Peter Stephensen Luebeck**  
Danish Plant Directorate / DK



**Erkki Vesanto**  
Plant Production Inspection  
Centre / FI

# ENGL Steering Committee

## Newcomers from Accession Countries



**Klara Dallmann**  
Godollo Agricultural  
Biotechnology Centre -  
Environmental Biosafety  
Research Institute / HU



**Ioannis Ioannides**  
Agricultural Research  
Institute / CY



**Vacloovas Jurgelevicius**  
National Veterinary Laboratory / LT



**Merike Kelve**  
National Institute of Chemical  
Physics and Biophysics / EE



**Nadia Lanzon**  
Environment Protection  
Directorate / MT



**Jaroslava Ovesna**  
Research Institute of Crop  
Production / CZ



**Ieva Rodze**  
State Veterinary Medicine  
Diagnostic Center (SVMDC)  
of Food and Veterinary Service / LV



**Peter Siekel**  
Institute for Molecular Biology of  
Slovak Academy of Sciences / SK



**Barbara Tudek**  
Institute of Biochemistry and  
Biophysics Polish Academy  
of Sciences / PL



**Jana Zel**  
National Institute of Biology / SLO

Note: Members of the Steering Committee not pictured here are Marcel Bruch (Ministère de la Santé, LUX), José Juan Sánchez Sáez (Centro Nacional de Alimentación, SP), Martin Sandberg (National Food Administration, SW)

# Appointed Laboratories

## Austria

- AGES Landwirtschaftliche Untersuchung und Forschung Wien (LWVIE) / Wien
- AGES - Lebensmitteluntersuchung und Forschung Wien (LUVIE) / Wien
- Umweltbundesamt GmbH (UBA) / Wien

## Belgium

- Ministry of Social Affairs, Public Health and Environment. Scientific Institute of Public Health (IPH). Service of Biosafety and Biotechnology / Bruxelles
- Ministry of Small Enterprises and Agriculture. Centrum voor Landbouw Onderzoek (CLO). Department Plantengenetica en -veredeling / Melle
- Ministry of the Walloon region. Agricultural Research Centre (CRA). Quality of Agricultural Products Department / Gembloux

## Cyprus

- Agricultural Research Centre / Nicosia
- State General Laboratory / Nicosia

## Czech Republic

- Institute of Chemical Technology / Prague 6
- Research Institute of Crop Production / Prague 6
- National Institute of Public Health / Brno
- State Veterinary Institution Jihlava / Jihlava
- Czech Agriculture and Food Inspection / Brno

## Denmark

- Ministry of Food, Agriculture and Fisheries. Danish Plant Directorate (PDIR) / Lyngby
- Danish Veterinary and Food Administration. Institute of Food Safety and Nutrition (FDIR) / Søborg

## Estonia

- National Institute of Chemical Physics and Biophysics / Tallinn
- Agricultural Research Centre / Saku

## Finland

- Finnish Customs Laboratory - Tullilaboratorio / Espoo
- National Veterinary and Food Research Institute (EELA) / Helsinki
- Plant Production Inspection Centre (KTTK) / Loimaa

## France

- Institut National de la Recherche Agronomique (INRA). Centre de Versailles Unité de Phyto-pathologie et Méthodologies de la Détection de Versailles (PMDV). Equipe de Méthodologies de la Détection des OGM (MDO) / Versailles
- Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF). Direction des laboratoires. Laboratoire de Strasbourg / Illkirch Graffenstaden
- Laboratoire National de la Protection des Végétaux (LNPV) d'Orleans / Fleury les Aubrais
- Groupe d'Etude et de Contrôle des Variétés et des Semences (GEVES), laboratoire BioGEVES / Surgeres

## Germany

- Behörde für Umwelt und Gesundheit (BUG) / Hamburg
- Bundesinstitut für Risikobewertung (BfR) / Berlin
- Chemisches und Veterinäruntersuchungsamt Freiburg (CVUA) / Freiburg
- Robert Koch-Institut (RKI) / Berlin
- Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit-Außenstelle München Molecular Biology

## Greece

- Ministry of Finance. General Directorate of General Chemical State Laboratory Food Division (GCSL) / Athens
- Seed Testing Station / Maroussi
- Institute of Agrobiotechnology (INA). Centre for Research and Technology. Hellas, Themi / Thessaloniki
- Ministry of Agriculture. General Directorate of Animal Production Inputs. Section of Feedingstuffs / Athens

## Hungary

- National Public Health Center - National Institute of Food Hygiene and Nutrition / Budapest
- Godollo Agricultural Biotechnology Centre - Environmental Biosafety Research Institute / Godollo

## Ireland

- Ministry for Finance. State Laboratory / Dublin
- Ministry for Agriculture, Food and Rural Development. National Crop Variety Testing Centre / Dublin

## Italy

- Istituto Superiore di Sanità (ISS). Laboratorio alimenti / Roma
- Istituto Zooprofilattico Sperimentale Lazio e Toscana (IZSLT). Dipartimento di Virologia e Biotecnologie / Roma
- Ente Nazionale Sementi Elette. Laboratorio Analisi Sementi (ENSE) / Tavazzano (Lodi)

## Lithuania

- National Veterinary Laboratory / Vilnius

## Latvia

- State Veterinary Medicine Diagnostic Center (SVMDC) of Food and Veterinary Service / Riga

## Luxembourg

- Ministère de la Santé. Laboratoire National de Santé. Division du Contrôle des Denrées Alimentaires (LNS) / Luxembourg

## Malta

- Environment Protection Directorate / Valletta

## The Netherlands

- Rijks-Kwaliteitsinstituut voor Land- en Tuinbouwproducten (RIKILT) / Wageningen
- Inspectorate for health protection and veterinary public health - Keuringsdienst van Waren (KVV) / Amsterdam
- Nederlandse Algemene Keuringsdienst (NAK) / Emmeloord



#### Norway

- National Veterinary Institute. Section of Food and Feed Microbiology (NVI) / Oslo
- Norwegian Food Control Authority (SNT) / Oslo

#### Poland

- Plant Breeding and Acclimatisation Institute Radzikow / Blonie
- Institute of Biochemistry and Biophysics Polish Academy of Sciences / Warsaw
- Institute of Genetics and Animal Breeding Jastrzebiec Polish Academy of Sciences / Wolka Kosowska
- State Sanitary - Epidemiological Station Tarnobrzeg / Tarnobrzeg
- The National Veterinary Research Institute / Pulawy

#### Portugal

- Instituto de Biologia Experimental e Tecnológica (IBET) / Oeiras
- Instituto de Tecnologia Quimica e Biologica
- Direcção-Geral de Protecção das Culturas (DGPC). Laboratorio de controlo de Materiais de Multiplicação de Plantas / Lisboa
- Instituto Nacional de Engenharia e Tecnologia Industrial (INETI) - Departamento Biotecnologia / Lisboa

#### Slovakia

- Institute for Molecular Biology of Slovak Academy of Sciences / Bratislava
- State Veterinary and Food Institute / Dolny Kubin
- Central Control and Testing Institute of Agriculture / Bratislava

#### Slovenia

- National Institute of Biology / Ljubljana
- Agricultural Institute of Slovenia / Ljubljana

#### Spain

- Agencia Española de Seguridad Alimentaria / Madrid
- IRTAGen - Servicio de Análisis Genéticos / Cambrils (Barcelona)
- Centro Nacional de Biotecnología. Campus de la Universidad Autónoma de Madrid (CSIC) / Cantoblanco (Madrid)

#### Sweden

- National Food Administration (SLV) / Uppsala

#### United Kingdom

- Food Standard Agency (FSA) / London
- Department for Environment, Food and Rural Affairs (DEFRA). Central Science Laboratory (CSL) / York
- Scottish Agricultural Science Agency (SASA) / Edinburgh
- Laboratory of Government Chemist Ltd (LGC) / Teddington



*Participants in the 3<sup>rd</sup> ENGL Plenary Session, held in Barza (Italy) on November 2003*

## View from the industry



Brussels, 13 May 2004

Dear Dr Van den Eede:

I am writing in response to your enquiry about a short contribution for your *Annual Report*. With the recent application of Regulations EC Nos 1829/2003, 1830/2003 and 641/04, the EU legislative framework for GMOs nears its completion. At all stages of the development of this legislation, we have called for centralised procedures - a key criterion for success in implementing this comprehensive legislation in a practicable and transparent manner.

In accordance with the GM Food and Feed Regulation EC No 1829/2003, we are therefore pleased to note that the European Food Safety Authority (EFSA) has been designated as the authority responsible for the safety assessment for GM plants, and the Biotechnology and GMO Unit of the Institute for Health and Consumer Protection at the Commission's Joint Research Centre's (JRC) as the Community Reference Laboratory (CRL) with primary responsibility for the validation of detection methods for GMOs.

We consider that the JRC, assisted by a consortium of laboratories in the EU Member States referred to as the European Network of GMO Laboratories (ENGL), has a major role in coordinating and establishing the standardised procedures for the validation of GMO detection methods. We are fully supportive of the important role that the JRC has played in accomplishing the work done to date. As a key stakeholder in this process, EuropaBio and its Member Companies note that there is still much to do and look forward to developing our collaboration with the JRC/ENGL to ensure that this particular aspect of the regulatory process is managed in a pragmatic, cost-effective and timely manner.

Yours sincerely,

**Simon Barber**

Director, Plant Biotechnology Unit

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## View from a researcher



Ministério da  
Agricultura, do  
Desenvolvimento Rural  
e das Pescas



DGPC  
Direcção Geral de Protecção  
das Culturas

Lisbon, 19 July 2004

Dear Dr Van den Eede:

I am writing in response to the request for a contribution for the European Network of GMO Laboratories (ENGL) *Annual Report* about the "View from a researcher on the Network".

Since the Network exists researchers note a strong progress towards:

- 1) the cooperation between experts of different but related areas on the GMO field. Experts from the Food/Feed and from the Seed sectors together with experts from the Biotechnology and GMO Unit of the Institute for Health and Consumer Protection at the Commission's Joint Research Centre's (JRC) as the Community Reference Laboratory (CRL), following the Commission Regulations and Recommendations have been supervising several distinct highly important subjects in order to strengthen the implementation, on the field, of the "GM policies";
- 2) the development of methods through the participation in several European funded projects;
- 3) the validation and harmonization of methods amongst the network laboratories.

They also note the need to upgrade the capabilities and capacities, mainly of the enforcement laboratories of the competent authorities, through their accreditation under a suitable accreditation (or certification) system, in order to improve the legal basis for effectively functioning on the GMO control. Related to this subject, researchers considered crucial all the assistance given by the JRC in coordinating training courses and consultation.

Researchers fully supported all the recent initiatives of the JRC in the acceptance of the new labs from the recently integrated Member States in the Network and in accomplishing collaboration with all involved researchers.

All together look forward to improve this great collaboration

Yours sincerely,

**Eugénia de Andrade Silva**

PhD, Responsible Researcher of the Laboratory for the  
Characterization of Plant Propagating Material

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*ENGL is a very important and good platform to discuss all the problems in the field of GMO analysis and therefore a tool for the harmonisation of the analysis and the regulation of the results of GMO analysis.*

Klaus Pietsch, Germany

*To a representative of the (up to know) smallest EU - Member State, ENGL has been a motivation booster to implement GMO detection laboratory in my Country.*

*The high quality of the scientific discussions, set up in a mediterranean atmosphere, generates (scientific) inspirations, highly appreciated in my home Country.*

Gilbert Moris, Luxembourg

*ENGL is an important body through which MS and Accession Country get an access to updated information about technical and legislative issues concerning GMO and it's also a platform to set up or improve detection methods, and to disseminate them in EU Countries.*

Barbara Tudek, Poland

*I have got new information used for establishing GMO control system in Czech Republic; fresh information about the progress in e.g. sampling strategy, reference materials etc.; the opportunity to participate in KELDA Project; to opportunity to meet experts from other Countries and to share experience and information about the accreditation of GMO laboratories.*

Katerina Demnerova, Czech Republic

*Each speciality within GMO testing (e.g. feed, food and seed) has different ways of viewing the problems associated with GMO testing. ENGL provides a forum, which allows these specialists to formulate methods and solutions to find a way forward for the benefit of all.*

Vincent Mulholland, UK

# Introduction on GMOs





The participating laboratories of the ENGL are involved in the analysis of plants and their seeds to check if they have been produced by genetic engineering and they analyse food and feed to check if they have been derived from genetically modified crops. This work is technical and very complex, therefore we will try here to explain what a GMO is and what makes it different from a traditional crop, how analysis is being done and why it is so important that we have robust and efficient methods in place that can be used across the EU — and beyond — in a harmonised manner.

### What is the difference between a traditional crop plant and a genetically modified crop?

Genetically modified organisms, or GMOs, differ from all other organisms by the fact that they carry pieces of genetic information (DNA) that originates from another species with which they would not be able to cross in nature. Whereas normal sexual propagation can only occur between closely related species, this does not apply to GMOs: the creation of a GMO may bring together pieces of DNA from totally unrelated species, e.g. DNA may be taken from a bacterium, a virus, or may be taken from a human or animal cell and put into a crop plant.

Insect resistance maize for instance, has been obtained by inserting a piece of DNA that has been cut out of a bacterium into a traditional maize variety. This bacterium, known as *Bacillus thuringiensis*, produces a toxin which, when ingested by larvae of certain insects, destroys their stomach and kills them. Sprays are being sold that contain high concentrations of this bacterium to use in order to combat insects. But once sprayed, the bacteria do not stay long on the plant leaves, with wind and rain soon eliminating them. Therefore, researchers have inserted this characteristic into maize plants, which is now marketed in the EU as well as in most parts of the world.

### How are genetically modified plants (GMPs) made?

To obtain a GMP, DNA from another, non-related species must be introduced into the genome of the host plant. For practical applications, the “foreign” DNA must remain stable, and be heritable, i.e. it should be passed to all offspring.

In most instances the foreign DNA is inserted into plant cells that are cultured in laboratory dishes after their cell walls have been removed. These cells are known as “protoplasts”.

Once a protoplast has been obtained, the process of introducing DNA into them can begin. There are two main ways for stable insertion of foreign DNA into protoplasts. The first one **uses a bacterium**, named *Agrobacterium tumefaciens* as an intermediate delivery vehicle. In nature, *A. tumefaciens* colonises a wide range of plant hosts, often transferring a piece of its own DNA into the host plant cells where it is incorporated into the hosts genome and causes the plant to produce sugars of nutritional value for the bacterium. The consequences of these events are commonly observed in nature as swellings, or galls, on host plants. Scientists have modified this system for the purpose of plant genetic modification and have applied it successfully to a wide range of plant species, excluding however agronomical important crops such as cereals. Cereals however may be genetically modified by **mechanical means**, such as the injection of foreign DNA or the application of ballistic guns that shoot DNA into the plant nucleus.

Once single plant cells are modified, they are grown in tissue culture, until finally, entire plants can be regenerated. Since all offspring originate from a single cell, the term “clone” is used correctly. The clones all contain the same piece of foreign DNA.



### First generation GMOs or ‘input trait’ crops

Examples of the ‘first generation’ of GM crops include pest resistant Bt cotton, which — as explained above — uses a soil bacterium (*Bacillus thuringiensis*) that produces toxins against insects. Also herbicide-tolerant soybeans which have been developed to resist non-selective herbicides, including glyphosate (mainly by using genes isolated from micro-organisms) belong to this group. So far, the vast majority of commercially released GM crops are first generation applications that mostly aim at providing on-farm benefits.

## Second generation GMOs or ‘output trait’ crops

A ‘second generation’ of GM crops aims at providing new value-enhanced or ‘output’ traits that improve the quality of the product to food producers or consumers. They may improve nutrient content, flavour, processing or storage characteristics. Examples include high oleic acid soybeans that contain less saturated fat than conventional soybean oil, high sucrose soybeans that improve food quality by improving taste and digestibility, and potatoes resistant to browning.

## Third generation GMOs

A ‘third generation’ of GM crops may be used for industrial or medical purposes to replace or enhance existing production systems. Examples include biologically-based plasticisers and lubricants, pharmaceuticals (e.g. production of vaccines in crops), and nutraceuticals or ‘functional foods’ (where food crops contain pharmaceutical properties such as disease-preventing micronutrients). An example of an existing nutraceutical is a strain of rice modified to produce pro-vitamin A, which can assist in reducing the incidence of blindness. Another example is canola oil with high beta-carotene content.

## Safety assessment

Safety has utmost priority and therefore, genetically modified food, food additives, animal feed and processing auxiliaries are subject to comprehensive safety tests before they can enter the marketplace. Applicants for a marketing license are obliged to show, on the basis of tests that have been conducted, that the products in question do not entail any risk to humans, animals, or the environment.

## Tracing, monitoring and labelling

Whereas a product can only be approved for marketing when considered as “safe”, GM plants need to be monitored after their marketing approval and eventual effects on the environment and on human and animal health need to be spotted. In addition, modern food production — particularly in case of food and feed produced from GMOs — need to be traced from the site of production (the farm) to the site of consumption (the fork). Finally, food and feed derived from GMOs (or containing GMOs such as yoghurt containing genetically modified *Lactobacillus*) — need to be labelled.

The need to monitor, to trace and to label, in other words the need to verify the presence and amount of GMOs in agricultural crops, and in products derived thereof, has generated a demand for analytical methods capable of **detecting, identifying and quantifying** either the introduced DNA, or the protein(s) expressed, in transgenic plants. In addition, for certain types of GM food such as vegetable oils with altered fatty acid profile, chemical analysis, such as chromatography and near infrared spectroscopy may be a complimentary or alternative tool for GMO detection.

In general this process consists of three different steps (see figure one in annex):

**Detection** (screening of GMOs), in order to gain a firsthand insight into the composition of the food and agricultural product. Analytical methods for detection must be sensitive and reliable enough to obtain accurate and precise results in all control laboratories, which can be achieved through inter-laboratory validation.

**Identification** to reveal how many GMOs are present and, if so, if they are authorised within the EU (or other countries with regard to their regulations). A prerequisite for the identification of GMOs is the availability of detailed information on their molecular make-up. Molecular registers that, along with the scientific data, contain the necessary data (confidential) for control authorities to design appropriate identification methods are essential to fulfil this task. The European Commission, Joint Research Centre is in the process of setting up such a database, for exclusive and private use by EU National Competent Authorities.

**Quantification**, in order to determine the amount of one or more authorised GMOs in a product or seed lot, and to assess compliance with the threshold regulation. For this approach it is necessary to get a better understanding of DNA/protein degradation during processing and of the robustness of the analytical methods.

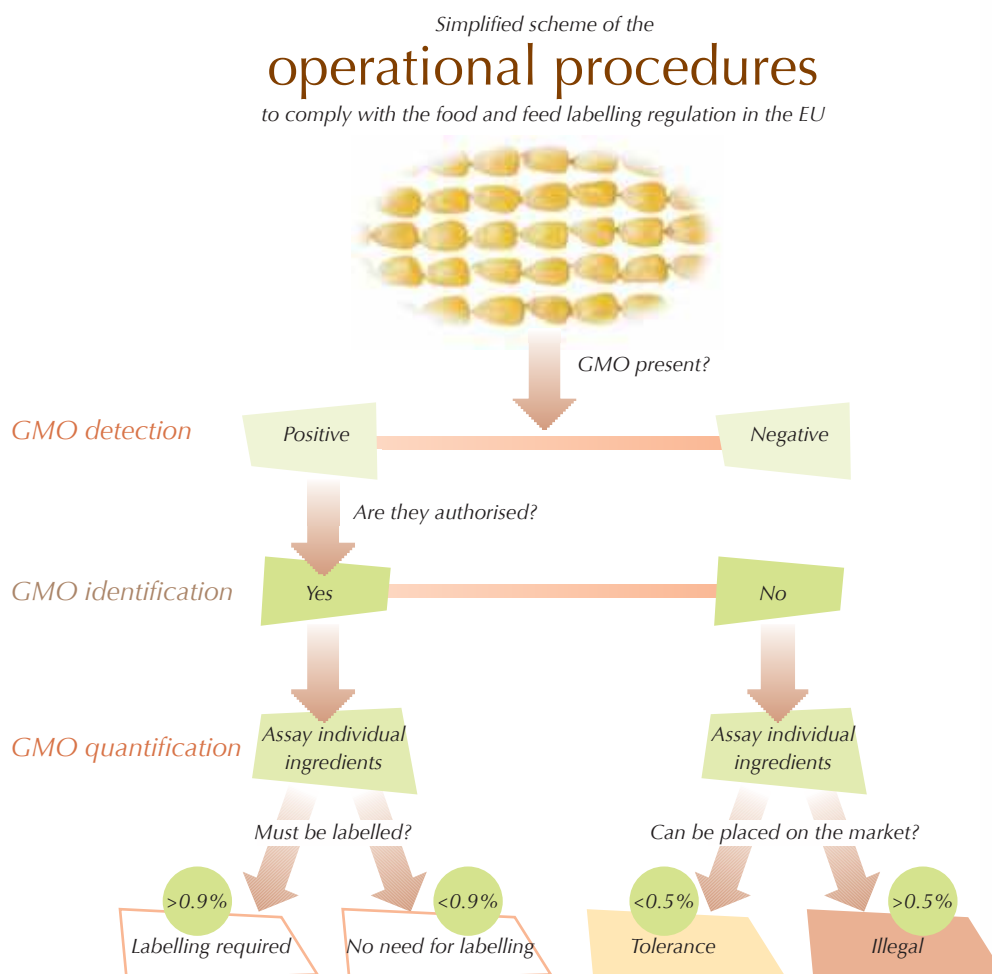
The European regulatory system relies upon the availability of validated analytical methods. The objective of validation of an analytical GMO method is to demonstrate that the successive/combined procedures of sample extraction, preparation, and analysis will yield acceptably accurate, precise, and reproducible results for a given analyte in a specified matrix. Depending upon the intended purpose of the analysis, i.e. qualitative screening or quantification, different validation parameters have to be evaluated.



Method validation is a lengthy process, which, according to international standards, involves at least twelve different laboratories. It is also a process in which different players have different responsibilities, e.g. the notifier is responsible for submitting an optimised method to the method validator, but subsequently is no longer involved in the process. Currently, no GMO is allowed for marketing if there is no validated method available to control authorities. This work represents the core of activities of the European Network of GMO Laboratories.

Every new GMO requires a new analytical method. In addition, control samples need to be available for control authorities, because they need to interpret the results of an unknown sample, with a positive and a negative control sample. The JRC's Institute for Reference materials and measurements is the world's first for this production.

To summarize, the genetic modification of organisms provides fascinating prospects for a large variety of application in industry, agriculture as well as in many other domains. Careful assessment as well as control and monitoring is essential. It is the role of ENGL to show to governments, developers, industrialists and most of all to the general public that such control, although being difficult, can be carried out and is organised throughout the EU in a harmonious way.



*ENGL is a wonderful network of people having discussions at a high level of expertise. The diffusion of information within the Network, the exchange of views and the communication of scientific results, aim at making feasible the enforcement of the European legislation, relatively to GMOs.*

*In the same time it also contributes to harmonise the approaches of control laboratories all over Europe.*

Gilbert Berben, Belgium

*For me ENGL is a space in which the Members can share experiences, exchange ideas and discuss technical issues.*

*Within the ENGL we can also update information on method validation, CRMs production, research projects progress and regulation issues.*

David Zhang, France

*It is very important for me to discuss on subjects related to the GMO control problems, with people working in the same area.*

Marianne Monsted Jorgensen, Denmark

*E - "European" - Europe? Enlarged Europe? - Worldwide recognition!  
N - "Network" - Network? Sometime like a family, but most of the times a real (hard) working group*

*G - "GMO" - Our common interest, covering many aspects, leading to hot discussions*

*L - "Laboratories" - The places where we have to go back to, after we had the pleasant and interesting meetings at the JRC...*

Andreas Heissenberger, Austria

*ENGL: Point of reference! In the past many activities were going on in as many different labs in Europe.*

*Now there is a well-coordinated organisation that can prevent the duplication of efforts and greatly facilitates the exchange of views and experiences.*

Esther Kok and Henk Aarts, The Netherlands



## Overview of major activities





# Thresholds

## Labelling requirements for authorised GMOs

Under Regulations (EC) 1829/2003 and (EC) 1830/2003, products consisting of or containing GMOs, and food or feed containing, consisting of or produced from GMOs, or containing ingredients produced from GMOs, are subject to labelling requirements.

Exemptions apply to traces of authorised GMOs in products intended for direct processing (Article 7 of (EC) 1830/2003) and to foods containing material, 'which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient' (Article 12 of (EC) 1829/2003). The presence of such material must be adventitious or technically unavoidable. The same exemptions apply to feed. See also Article 47 of (EC) 1829/2003 establishing lower thresholds in certain cases.

A new Directive setting thresholds for the adventitious presence of GM seed in conventional seed lots is expected to be introduced in the near future. The Directive will be accompanied by a Regulation on a protocol for sampling and testing of seed lots.

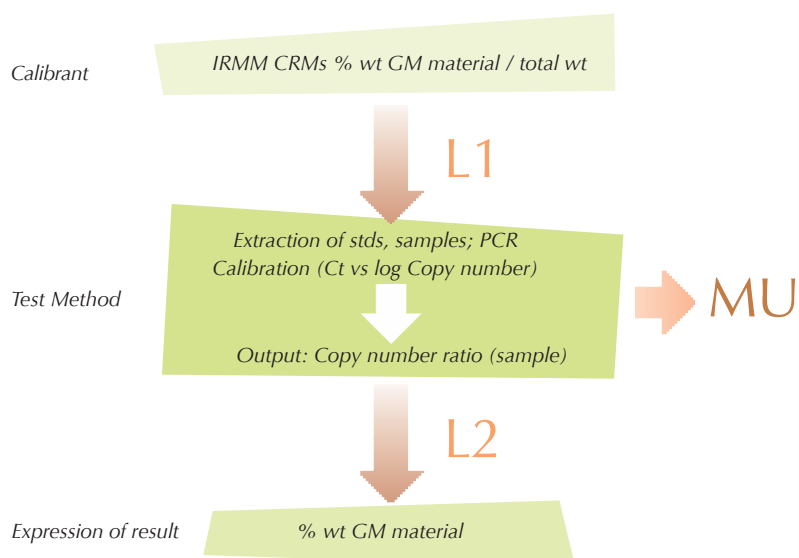
## Biological factors in the quantitation of genetically modified material

Currently used methodology for quantitative measurement of the presence of genetically modified material is based on Real Time PCR technology. In GMO quantitation RT-PCR is used to measure the number of copies of a target DNA sequence, specific to the GMO of interest, relative to the number of copies of a species-specific DNA sequence. However the reference materials used for calibration are usually based, not on copy number, but on a % wt. of GMO material, or DNA extracted from such material. Moreover, the results have to be expressed in terms of % GM material (material containing, consisting of, or produced from GMOs) on an ingredient basis, in order to determine compliance with the legislative thresholds. This is demonstrated graphically below.



## GM analysis

*E.g. Determination of % GM material in a food ingredient*



The relationship between % copy numbers and % by wt. of GM material is influenced by complex biological factors such as phenotypic expression, zygoty and, in the case of heterozygous seed material, whether the transgenic source is male or female.

If the relationship between % wt GM material and copy number ratio in the calibrant (L1) is different to the relationship between the copy number ratio and % GM material in the sample ingredient (L2), then there exists an added biological uncertainty over and above the analytical measurement uncertainty (MU). As the uncertainty in the final result needs to be taken into account in assessing compliance with legislation, it is important to consider these issues.

Moreover, traceability<sup>1</sup>, the property of a result of a measurement, or the value of a standard, whereby it can be related with a stated uncertainty to stated references through an unbroken chain of comparisons, is a requirement under ISO/IEC 17025. It helps to ensure comparability of results in space (between laboratories) and in time.

In the case of seeds it is possible to use a statistical approach, based on multiple sub-samples and the use of qualitative PCR, to assess compliance with thresholds that are defined on a % seed basis. This approach is highly reliable, but is considered both time-consuming and costly. If RT-PCR is applied to determine % GM seeds, then similar issues as those discussed above have to be considered.

### Barza Meeting

The first discussion group meeting on thresholds in the context of the GM legislation was held at the ENGL Plenary meeting in Barza, Italy, in November 2003. The meeting discussed the interpretation of the legislation and the biological issues. While there are no simple solutions to the biological questions, it was generally agreed that it was important to have full knowledge of the origin of genetically modified material used in preparation of reference materials, and that it was important to state the method and the reference material used when reporting results.

#### **Patricia Bonner**

State Laboratory  
Dublin (IR)

#### **Hermann Broll**

Federal Institute for Risk Assessment  
Berlin (G)

#### **Marc De Loose**

Centre for Agricultural Research  
Melle (B)

1. ISO Guide 30 and VIM (International Vocabulary of Basic and General terms in Metrology)

# Validation

## Validation in the light of ENGL

Before a GMO detection and quantitation method can be introduced into use by control authorities it should be validated in a collaborative trial with several participating laboratories. In a validation study, evidence that the method consistently meets the requirements for the intended application is obtained. A method, which is used for control purposes, should be properly validated to assure reliable testing results. In the past, European GMO testing laboratories have faced serious problems to obtain methods and necessary reference materials for GM testing. Therefore, it is natural that one of the main activities of the ENGL has been to improve the availability of validated methods for the testing.

In the last year, major progress was made thanks to the to the new regulations — in particular to the GM Food and Feed Regulation (EC) 1829/2003. For each GM authorization, the applicant has to submit — among other things — a method for detection, sampling and identification of the transformation event. The Regulation nominates the Joint Research Centre as the Community Reference Laboratory for the GM Food and Feed with the main task of validating the methods submitted by the applicant. The Regulation further states that the JRC will be assisted in this task by the ENGL. The ENGL assistance consists mainly of the scientific assistance and technical support to the CRL. In particular, the ENGL laboratories are the preferred partners in the collaborative trials organised by the CRL.

## Validation process

In principle, validation of analytical methods including GMO detection is a very important step and it is the absolute requirement according to international standards before it could be used for control purposes. It is the process of establishing the performance characteristics and limitations of a method and the identification of influences which may change these characteristics and to what extent. The main goals of validation are that the test results obtained with a certain method are accurate and precise, the methods used end with a result which is comparable with a result achieved with the same or a different method.

Specific performance parameters have to be tested before a method could be accepted as validated. Only the analyte under investigation should give a positive respond. In case an event 176-specific method is used, the result has to be negative, if only events other than event 176 are present in the sample. To decide if a method is “fit-for-purpose” the sensitivity needs to be analyzed, otherwise it could happen that a method with a limit of detection (LOD) of 2% is used to meet a 1% threshold. A negative result obtained with this procedure would probably lead to a wrong interpretation and decision by e.g. QS manager or competent authorities. Furthermore the trueness and precision have to be determined. The closeness of a result to a true GMO content is analyzed by using reference material. The deviation between the mean value and the true GMO content is typically expressed in terms of bias. Whereas the closeness of individual determinations with the same method and the same sample describes the precision of the method. If it is determined in-house it is expressed as the “repeatability” of the method. In case the same method is applied to a defined matrix in different laboratories it is called “reproducibility”. It is obvious that the latter one is very time and cost-intensive and will only be done if all other characteristics of the method under investigation are given satisfactory results.

As shown in the figure below, the usual process of “full”-validation could be divided into three parts:

- 1) the method development and optimization in a single laboratory;
- 2) a pre-validation study with a few laboratories (3-4) to get an indication, if the method works in different labs, and finally
- 3) the step in which the method is tested in a collaborative study with at least 12 laboratories to determine the precision under reproducible conditions.

All performance characteristics described above lead into a “fully-validated” method which will be the absolute requirement for food and feed control purposes. Moreover, the EN ISO/IEC



17025 standard describes general requirements for the competence of testing and calibration laboratories. Specifically, the need to use only validated analytical methods is described as a prerequisite to perform tests.

In contrast to method validation, proficiency testing is often mentioned, but the aim is totally different. By participation in a proficiency testing study a laboratory could demonstrate their competence to carry out GMO testing. In proficiency tests each individual laboratory can use any method established in the lab which is fit-for-purpose to detect and/or quantify the analyte under investigation.

### **ENGL Working Group Validation**

The year 2003 was a very intensive period for the ENGL working group validation. In the authorization context, there is a need for a clear approach, firstly, for accepting a method for the validation process and, secondly, for the minimum performance requirements, which a method should fulfil in a validation study in order to be accepted as fit for control purposes. In addition, the applicants need clear guidelines of what is expected from them, e.g. what is understood with a method and what are the matrices to be considered. During the year 2003 the ENGL elaborated the approach for the validation within authorization context. The work was initiated during the first ENGL Working Group meeting “Definition of minimum performance requirements for analytical methods” (Ispra, Italy, January 16-17, 2003). Thereafter, comments from the ENGL members were incorporated into the document on several rounds.

The draft document was made available in the ENGL web-pages, and scientific and technical comments from all interested parties were invited during the period 1.7/15.8.2003. Several comments mainly from all the major companies as well as governmental and research organisations were received. All the comments received were reviewed in ENGL Steering Committee meeting in September and considered in-depth in an ENGL Working Group meeting dedicated to the topic (Ispra, Italy, October 20-21, 2003). The approach, which is currently used by the CRL was accepted in the ENGL Plenary meeting in October 2003.

Towards the end of 2003, the ENGL experts were invited to express their interest in the work in a CRL expert group to establish the operational procedures of the CRL. This work commenced in early 2004 —and is a very good example of the ENGL assistance function to the CRL. Currently, a CRL advisory panel consisting selected ENGL experts is continuously assisting the CRL in scientific questions.

### **Development of the Modular Approach for Validation**

The so called modular approach for method validation has been developed and discussed within the ENGL in 2003. The original idea has been presented and published by Arne Holst-Jensen from the National Veterinary Institute of Norway. The idea is that a method refers to all the methodological steps needed to analyse the notified (or otherwise relevant) material. For a particular material this may include, for instance, the methods for DNA extraction and the final quantification in a PCR system. In such a case, the whole chain from extraction up to the PCR-method (or equivalent) constitutes a method, but the different method parts can be validated separately (i.e. modular validation). The idea of the modular method validation is that each method or protocol can be validated separately, and once validated, can be combined with other modules in a flexible manner.

The modular approach is incorporated to the CRL validation scheme, supported by the CAN approach of standardization and it is tested and developed further in research collaborations. For instance, an EU integrated project proposal COEXTRA (coordinated by Yves Bertheau from INRA) contains a considerable element in further developing the approach —and GM testing in general.

### **Bt11 sweet maize collaborative study**

During the 2003, the ENGL and the JRC concluded the first full validation study which was carried out for the GM authorization purposes. The collaborative study was carried out to test the performance of a quantitative event-specific method to detect and quantify the Bt11 transformation event in sweet maize. The method validated had been developed by the National Veterinary Institute of Norway and INRA, France, within the EU shared cost action project QPCRGMOFOOD. The 14 participants of the validation study were members of the ENGL from nine different European countries. The materials needed in the study (GM and non-GM DNA as well as the method-specific reagents) have been provided by Syngenta.

In addition, the pre-validation studies for the validation of detection methods for the GA21 maize and NK603 maize were initiated during the 2003.

**Hermann Broll**

Federal Institute for Risk Assessment  
Berlin (G)

**Janna Puumalainen**

JRC-B&GMOs Unit  
Ispra (I)



# Sampling

## Introduction

A GMO analytical service is carried out to gain information regarding the composition of a large body of target material. In contrast, a very small amount of material is subject to the analytical procedure. As a consequence, the sampling processes used to prepare the analytical samples are of paramount importance to ensure reliable and informative analyses.

Although guidelines defining sampling strategies for quality and purity analyses are available and currently adopted for GMO surveys, their suitability for GMO detection is questionable because of their stringent statistical assumptions with respect to the possible distribution of the contaminants. Indeed, most of these guidelines recognize that the procedures are not effective in the sampling of non-random distributions. Whilst lot homogeneity can be assumed for seed lots, traditionally subject to stringent protection methods for limiting genetic contamination and to smaller upper lot size limits to facilitate mixing and homogenization, it cannot be unconditionally assumed for grains and bulk commodities, which are more prone to segregation during transportation and handling.



Yet, given the lack of suitable statistical approaches to define sampling procedures appropriate for situations where standard statistical models cannot be applied, currently available sampling protocols continue to be used without verification of their assumptions. Nevertheless, when sampling is executed to check for compliance with legislation requirements, it is of crucial importance to ensure a high degree of confidence that the survey is accurate and that the sampling error is as small as possible.

Provided that understanding distribution patterns in kernel lots is a pre-requisite to develop and recommend suitable sampling plans with respect to European GMO legislative requirements, ENGL has initiated, and currently is carrying out, different initiatives to gain the scientific information necessary to support the achievement of harmonization of sampling plans in the different Member States.

## Research Projects

- ♦ **KeLDA** (Kernel Lot Distribution Assessment) is an ENGL collaborative pan-EU research project, coordinated by the Biotechnology and GMOs Unit, IHCP-JRC, designed to investigate the distribution of GM contaminations in soybean grain lots imported in the EU from different countries outside the EU. As a case-study, KeLDA represents the first project carried out to assess the real distribution of GM materials in soybean grain lots imported within Member States, and it is the first study to provide real data on this issue. KeLDA results will allow to assess the distribution of GM material in raw bulk materials, to evaluate suitability of currently adopted sampling strategies for the detection of GM material in bulk lots, and to provide recommendations for implementing sampling strategies to ensure effective sampling. Up to date, 12 soybean lots have been sampled and analyzed for the presence of GM material. A preliminary analysis of the results obtained so far indicates that distribution patterns do vary among lots and do show heterogeneity.
- ♦ A new approach to investigate the effects of different levels of heterogeneity on the accuracy and suitability of different sampling plans for the detection of GM contaminations within kernel lots was developed. The approach is based on a two-step procedures that



allows first, to create virtual kernel lots with different levels and distribution patterns of GM contaminations and second, to test different sampling strategies. The flexibility of the model allows the simulation of large kernel lots without imposing any constraint on the distribution of GM contaminations. As a result of this flexibility, the effects of different levels of heterogeneity can be assessed, through simulations, on the accuracy and suitability of different sampling approaches for the detection of GM particles within kernel lots.

- ♦ To support and further develop the approach described above, an exploratory software - **KeSTE** (Kernel Sampling Technique Evaluation), designed to evaluate sampling strategies as function of lot properties in case of non-random distribution of contaminants was developed and distributed to ENGL members. The software is available free of charge on the ENGL website. KeSTE allows the evaluation of different sampling strategies on both simulated lots, with user-defined characteristics (exploration of hypothetical scenarios), and on real lots. This first version of KeSTE should be considered a preliminary one, meaning that some part of the code must still be optimized, and other must be still added. This is not due only to the state of development of the software, but also to the state of development of the conceptual models behind KeSTE, which are continuously evolving as a consequence of the use of the software itself. As a result, the software target users are researchers with some experience in sampling theory and practice. When the conceptual models will be consolidated, we can foresee the development of a derived, user-friendly version targeted to a more applied rather than explorative evaluation of sampling.

### Technical Advice

Among ENGL priorities there is also the provision of internal support and external advice on focused issues to regular network committees and expert working groups on an ad hoc basis. In particular, during the last year of scientific activity, ENGL experts have provided technical advice to

- 1) the DG SANCO “Working group on seed legislation, sampling and detection” for the definition of a protocol for the sampling and detection of GM seeds in seed lots and
- 2) to DG ENV and DG SANCO for the preparation of the Commission Recommendation on technical guidance for sampling and detection of GMOs and material produced from GMOs or in products in the context of the Regulation (EC) n° 1830/2003 and
- 3) to CEN with respect to concerns raised by ISO regarding the compatibility of sampling plans for foodstuffs proposed by CEN (discussion paper CEN/TC 275 WG 11 N 0059) with other internationally adopted sampling protocols.

**Claudia Paoletti**  
JRC-B&GMOs Unit  
Ispra (I)

Reduction of sampling error



Representative sample



Sampling protocol

*Free of distribution assumptions*



Lot



# Certified Reference Materials

According to the EC regulations food or food ingredients containing GMOs (Genetically Modified Organisms) must be clearly labelled. Certified Reference Materials (CRMs) are indispensable tools to accurately determine the concentration of GMOs used for the production of food. In 1997, the Institute for Reference Materials and Measurements (IRMM) developed, produced and certified the first ever reference materials for GMOs to support reliable and comparable GMO identification and quantification. Until now three generations of matrix GMO CRMs for various GMO events in maize and soybeans have been produced in accordance with ISO Guide 34: Roundup Ready® soybeans (IRMM-410S), Bt-176 maize (IRMM-411R), Bt-11 maize (IRMM-412R), MON810 maize (IRMM-413), GA 21 maize (candidate IRMM-414) and NK603 maize (candidate IRMM-415). In general CRMs matrix CRMs like the GMO powders are designed for the verification of the correct application of standardised methods. Several of the powder GMO CRMs were also used for the development and validation of screening and quantification methods for GMO food. In addition the IRMM is currently developing methods to certify pure DNA CRMs suitable for the calibration of DNA-based measurements.

The certification of the GMO concentration in the matrix CRMs is based on the dry mass of GMO powder in dry non-GMO powder. During the certification procedure the gravimetric values are verified by application of commonly used GMO quantification methods targeting the transgenic DNA or the transgenic protein.

Thorough control of the raw material is the first production step of a GMO CRM and is of high importance for all fields. GMO and non-GMO raw materials need to be of highest purity with a defined genetic composition.

Contamination during the production process is avoided using targeted production equipment. Another crucial point is the grinding of the seeds to a particle size allowing homogenous mixing. For the production of the 3<sup>rd</sup> generation of GMO CRMs with high DNA/protein quality a dry-mixing technique was developed. The well-characterised GMO powder is diluted stepwise with non-GMO powder during this production step. The powders with different GMO concentrations are afterwards bottled under appropriate conditions. Verification measurements for the GMO concentration and homogeneity and stability controls are carried out.

Homogeneity and stability are of utmost importance for the certification of such reference materials in order to ensure validity of the certificate for each bottle of a batch throughout a defined shelf-life. These characteristics ensure comparability of a certain CRM batch. Traceability to SI systems or other stated references are essential for the international comparability of CRMs and to ensure that they can be reproduced. For the GMO powder CRMs traceability is ensured with the gravimetric approach used and the characterisation carried out.



**Stefanie Trapmann**

JRC-IRMM  
Geel (B)

*ENGL has formed a very good floor that allows an efficient action of individual laboratories. Due to high level research, validation studies and information dissemination better approaches can be employed to solve gmo ? (vedi form) topics. Especially for Czech laboratories ENGL is a rich source of experiences, that are applied to improve control process.*

*The possibility of participating in the ENGL projects (e.g. KELDA Project) is a great opportunity.*

Jaroslava Ovesna, Czech Republic

*ENGL is a network that demonstrates the strength of working together to achieve an end result. To date the activities of the members, we have been able to bring about a co-operative working forum that seeks to promote excellence in analytical competence and to share experiences in GM analysis and regulation throughout the EC.*

*The community has granted ENGL legal status to pursue its activities in recognition of the significance of this work and it is evident that Member States will benefit from its continued operation.*

Sarah Oehlschlager, UK

*ENGL has been a place of exchange of information, experiences and discussion and a seed of new ideas, all in a warm and friendly atmosphere.*

*The importance of this for our daily work is not measurable.*

Teresa Crespo, Portugal

*To our perception the ENGL is acting as a scientific and technical network.*

*This was felt mainly by:*

*1) the exchange of information within its members: we appreciated the organisation of different working/discussion groups. They had a great contribution for the excellent annual results also obtained by our laboratory*

*2) the participation in European projects*

*3) the exchange of experiences with experts from the Accession Countries was also relevant: this leaded us to bilateral co-operation projects.*

Eugenia De Andrade Silva, Portugal

# Interview



During the 3<sup>rd</sup> Plenary Session of ENGL, held in Barza (Italy) in November 2003, an exchange of views on ENGL took place between William Moens [WM] (Institute of Public Health, Brussels) and Katerina Demnerova [KD] (Institute of Chemical Toxicology, Prague), moderated by Rossella Speroni [RS] (Joint Research Centre, Ispra). At that time Accession Countries were not ENGL full members but observers.





**R.S. How do you perceive the ENGL Network?**

**K.D.** Being a member of the ENGL is really important to my country. We joined it two years ago, after receiving the official invitation to participate in a meeting of the Network. Together with Bulgaria and Poland, we were the only socialistic country in the Network at that time. Getting into the ENGL has been a first step towards a new way of working, because we had the opportunity to learn from other colleagues how to study and checking the GM food, as, in my country, we did not have a proper network of laboratories to do so. Regarding the exchange of information and support within the network, I would like to say that Guy is very open. He gave Kamila, a Czech

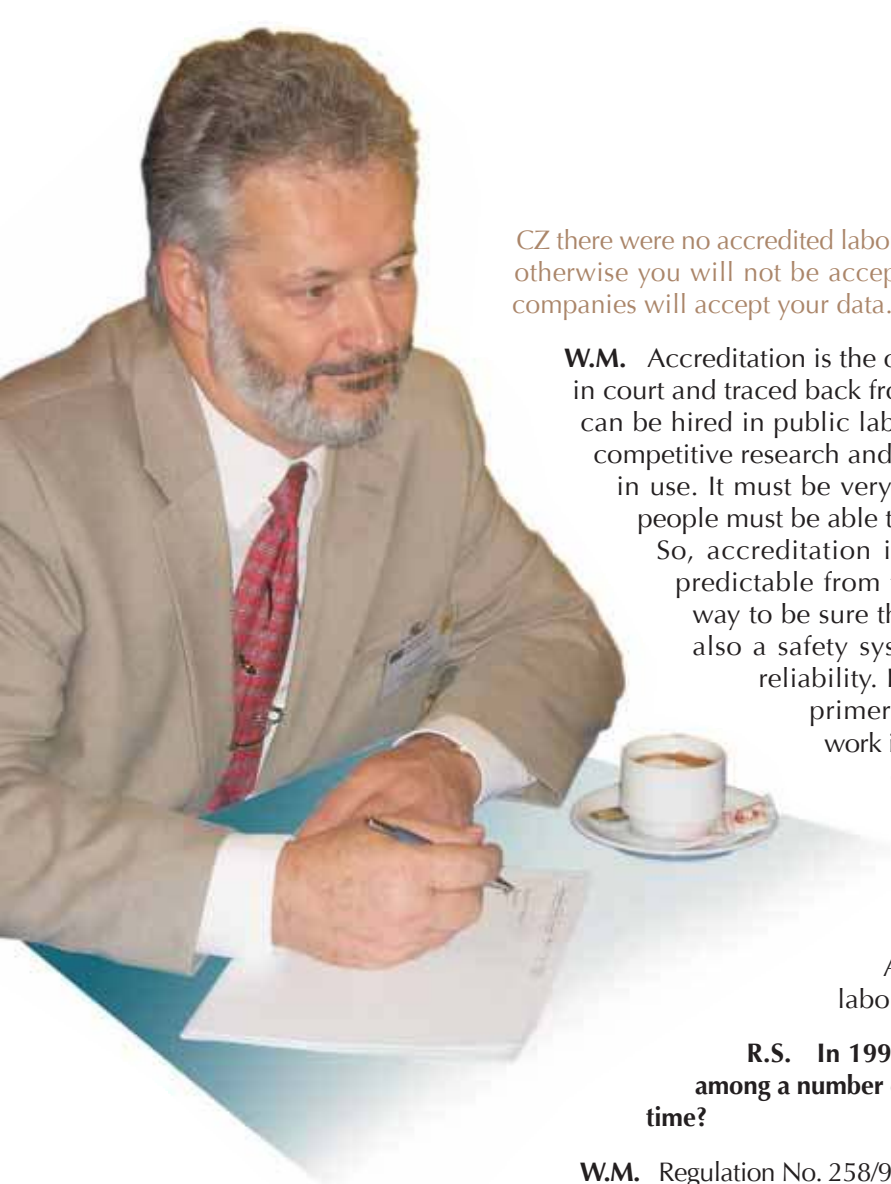
researcher working now in our laboratory in Prague, the opportunity to work for nearly ten months in his laboratory in Ispra and to learn the techniques of sampling, which to me is very important for the estimation of GMOs. I believe it is of the utmost importance to connect all laboratories working on GMOs in my country, so as to share all information my laboratory receives as a member of ENGL; for this reason I am waiting for the accreditation that is foreseen for next year.

**R.S. Accreditation is a relevant matter for GMOs laboratories. Could you explain something more concerning accreditation?**

**W.M.** Accreditation is an interface between laboratory activity and the regulatory framework. In my country, analysis of data are acceptable only if they are produced by accredited laboratories. All other data are interesting but not legally useful. For enforcement, data has to be defendable in court. As a consequence, in Belgium, the top priority is to first establish a network of accredited labs and afterwards one of non-accredited laboratories. For my laboratory, accreditation has been the key to becoming a valuable partner of the Belgium Authorities. We have several Authorities and several regulatory frameworks as well. These Authorities do not all have the same perception. Food safety is more in the context of food quality, quality management of the food chain and environmental monitoring. The ENGL priority is the food chain and the regulation deriving thereof. Environmental aspects are of less importance. From the cost point of view connected to the experimentation phase, this entails a totally different approach. Accreditation is the only way to actively contribute to the success of the role the CRL, which has been given by the EU Regulation in the field of GM foods and feeds. In Belgium, the existing ISO7025 standard provides for an interaction between laboratories using standard procedures and institutions so that the information and administrative data could be well maintained and predictable. The ENGL will help the work of accredited labs and the CRL.

**K.D.** We have experience with accreditation as for microbiology and classical microbiology for the testing of food. But if we compare it with the accreditation for GMO testing the base could be the same but the practical method is completely different and much more difficult to establish. Accreditation is the more important step to take before being able to work in combination with other laboratories. At the very beginning, in





CZ there were no accredited laboratories. Nowadays, you have to be accredited otherwise you will not be accepted and cannot do anything without it. No companies will accept your data.

**W.M.** Accreditation is the only way to get data that could be defended in court and traced back from the quality point of view. Scientists who can be hired in public labs are not of the type you could find in top competitive research and we therefore have to adapt the technology in use. It must be very simple to manage, predictable and these people must be able to use it safely from the result point of view. So, accreditation is also a disciplinary step to make a lab predictable from the management viewpoint, it is the only way to be sure that the results are correct. Accreditation is also a safety system for the quality of the data and their reliability. If the CRL sends control samples with new primers they would need to know whether this work is in accordance with procedures, regulations etc. Trust is vital, as, if something is found to be wrong one has to rely on the other's judgement otherwise it will create total confusion. Accreditation is a guarantee that the standards of quality of the work are respected. Accreditation is a way to ensure good laboratory practice.

**R.S.** In 1999, what was the idea lying behind a meeting among a number of CAs as the ENGL was intended to be at that time?

**W.M.** Regulation No. 258/97 provided for a threshold to prove adventitious contamination of food by GMOs. In that context there was a clear need for measurement. But what? How? For which level of confidence? It was not obvious at all. Some people around the table, like Bertheau, Broll and myself, "the starters", concluded that if we were not able to co-ordinate in one way or another and get the authorities to sustain us it would have been impossible to comply with the regulatory requirements. It seems the words we exchanged at 2 o'clock in the morning in front of a bottle of grappa were convincing. Six months later not only the CAs but also the internal co-ordination of the Commission was working; a miracle. Everybody was laughing at me when, during Mr Busquin's speech at the Inauguration Ceremony of ENGL in Brussels last year, I said that it was something to write in the Guinness Book of Records.

**R.S.** Would you have ever figured out that the ENGL could become the network it is now? What were your expectations?

**W.M.** No expectations. We are people working for administrations, therefore, we know what the real life is. Communication is of great importance. Maybe we wanted to express our needs and be understood. This phenomenon was repeated during each meeting. Now the people in our group have become friends, they communicate with each other and they are respectful towards each other, this helps. It helps in speeding up the process. In 1999, we could have never imagined that after 3 years we would have had such means, ideas, vision, unity, and convergence of practical ideas. These are not academic discussions but day to day problems in life.

**K.D.** I also appreciated this environment a lot. You have a lot of committees in the group. At an academic level one talks a lot but at the end of the day you often do not have a clear conclusion. Nothing to pass on to my lab people. On the contrary, when I go back to my lab after having taken part in an ENGL meeting, I am able to improve the work of my staff and my communication with other labs. That is totally unique.

**W.M.** This is the European spirit: people converging to build something together. One feels it in the daily work. This is no philosophy. No politics or ideologies but day by day practice.

**K.D.** And it does not matter where the person is coming from. It is open (here she speaks about Norway and the fact this country is not yet a full member of the EU). It does not matter. There is no difference between member and non-members. Non-members need to attain the same level of knowledge. Maybe not totally the same but as close as possible. We should be able to interact on the same level and to exchange our know-how trustingly. ENGL has a very wide perspective and looks into the future.

**W.M.** Unique to the ENGL dynamic, indeed. In the structure of the EU, laboratories are not partners of the political decision or political vision. Policy executives of the CAs or companies have no voice in technology and the way it is applied. In the ENGL it's exactly the contrary. All these labs get instructions from the top; they have the horizontal ability to talk to each other to define commonalities and problem, to formalise this in a readable way, to communicate with the outside and go to the headquarters to deliver the message to the authorities. This is new! It does not happen in the medical, pharmaceutical and environmental area. It is the first time, I guess, unknown labs can speak to each other and communicate to "the high and mighty". We are building a validation network. We apply research to genetics. We have a lot of genetic markers. These might change but the technology remains the same. We build the network not only of experts but also of accreditation experts and network accredited experts. This is a unique tool in the world. Our Union has an original validation system, which is highly powerful not only for GMOs but also for all kind of genetic markers.

**K.D.** *(She speaks about the great opportunity to apply for FP6 projects as another way of interacting, even if W.M. refutes that the miracle of ENGL is not necessarily reproducible elsewhere). I like the idea that people work together on the same project with the same aim.*

**R.S. Something about the importance of the Reference Materials (RMs).**

**W.M.** RMs have to be evaluated from both a scientific point of view (their role in the scientific context) and the regulatory one (their importance, the responsibility of the companies to deliver good and appropriate RMs).

**K.D.** According to our experience, when we started the accreditation process we realised that to validate methods accurately we did need appropriate RMs. In CZ, Monsanto and some other companies, which are producing GMOs, are asking for permission to place these products on the Czech market. To do so, they have to declare that they will be providing the sequences of the relevant primers. Obviously this will be strictly confidential but they will have to guarantee that they will supply the labs with the appropriate control materials. It has happened previously that we have bought RMs which were not accurate and therefore we did not get the right results. So sampling, in my mind, is very important. It is a crucial step of our accreditation process. It is vital to estimate correctly transgenic DNA.

**W.M.** Do you think that ENGL has been able to influence the companies to better define RMs?

**K.D.** I think so. I think ENGL could serve as a benchmark and could play the role of an inspector. In this way, the companies feel under pressure. For instance, American companies that would like to place on the market products derived from GMOs are now aware of the fact that



they must respect fixed rules, they must respect the advice from ENGL and the opinion of the labs ENGL has brought together.

**W.M.** I agree. I am not against the companies but in the interest of the consumers, we need predictable GMOs, predictable laboratories, we need transparency. This is a key issue to which a large amount of our funding is being committed.

**K.D.** Exactly. One of our major challenges is to protect the public against the spreading of wrong information and products. People's perception is very important above all in the GMO field. If you tell a lie once, people will lose their trust in you.

**W.M.** Credibility is the number one priority. This is a really important message to deliver. If authorised, GMOs are perceived as products deriving from top technology, as they are indeed, also the top regulatory management and top information ensuing thereof are a symbol of their quality. GMOs are certainly the best controllable and traceable products existing nowadays. GMOs are traceable by default because of their genetic modification. The public may have not believed in this at the very beginning but I am sure that the birth of ENGL added a piece to this puzzle and will certainly improve the credibility of these unknown products.

**K.D.** In the future, I think GMOs will play a crucial role in food and non-food fields. This is why we have to build a trustworthy system to avoid any fear from the consumers' part. They must feel confident, they must say: "I can eat this, it is safe. There is a good control system. If the product has been placed on the market it must be safe otherwise it would not be commercialised".

**W.M.** It is again evident that we need robust reference materials. For the company, the CAs and ENGL.

**K.D.** In connection to RMs, I would like to have more information on the plasmid RMs.

**W.M.** In December 1999, at the ILSI meeting in BXL, I proposed that the analyte of traceability in case of GMOs were the genetic markers most of the time (or epitopes more rarely). In such a way that the analyte could be purified and become a kind of canonical RM from the genetic viewpoint, we would have access to a bank of RM from the genetic / matrix point of view. Therefore, we started to clone all genetic markers involving traceability. The advantage of such an approach is that the cloning and availability of RMs are totally controllable by the CAs. They can synthesise the markers by themselves, they can obtain the plasmids very rapidly with the guarantee of purity and from the validation point of view. This is totally independent from the good or bad will of the companies or providers. Well, this in theory... In practice, if someone wants to use these genetic markers they have to be commutable. It should be demonstrated that they could replace classical RMs. We are still trying and demonstrating that it is possible to interchange classical RMs, certified RMs, genomic DNA and plasmids. But it is a matter of months not years! It is ENGL philosophy to use validated stuff only (i.e. materials and methods). We have to make a proficiency testing of these plasmids used as quantitative or qualitative RMs and then we have to deal with them and distribute them to the ENGL community and to all those who surround the ENGL. But this is still under discussion.

**K.D.** Any foreseen trials?

**W.M.** Our plan is to, first of all, build a model/set of plasmids that could be used in proficiency testing, and / or for identification, and/or for quantitation. We now know that we can combine all three aspects within one genetic marker. Granted that the amplicon of Real-time PCR is the way to detect, identify and quantify at the same time, all genetic markers are available to do so. Now we are working on some of them and a small network of seven laboratories has been constituted. Amplicons are being collected and cloned in my laboratory. We can now use plasmids all in the same way and deposit them in an official collection system. We should provide the JRC with the set of DNA (December, January 2004 max.) and we have to set up the project for the proficiency testing, what the test will be, the time frame available to answer to the relevant questions etc. The lab itself could be also tested for its ability to screen and not to quantitate. For example, if I give you a mixture of GMOs, how many weeks, days, hours will you need to exactly list these GMOs one by one? Which ones and in which proportion? Is there one exceeding the fixed threshold? This is the real challenge! By using the plasmids you can play with their combinations! In this mixture we have seven GMOs:



which ones? And in this one you do not know their number and nature. Just do it. You have two weeks.

**K.D.** This is interesting. Is it possible, in your mind, to make it in two weeks?

**W.M.** I do not know! We have to demonstrate if this is realistic and feasible. We have to realise that the screening is the number one step to face for all labs. Due to the threshold regulation we have been investing a lot of time in Real-time PCR. But screening!!! Would serve to obtain the highest results with the minimum investment of money. And when you find something that is above the 0.5% threshold you will go for Real-time PCR or pass this work to another laboratory within the network so that we do not all invest on the same activities. We are in the process of preparing a report for the end of March 2004 so that when the regulation will enter into force the plasmid analyte will be ready. We do have to provide professional standards. Therefore, either IRMM in Geel will instruct how to produce, control, certify and distribute or we will have to design other types of mechanisms to use them. It could also be format for Real-time PCR. We could publish calls for tenders asking companies to provide plates, buffers plasmids etc. so that we will just have to have the primers and test the DNA.

**K.D.** You have to be accredited, too.

**W.M.** Yes, of course. In my accreditation system we are already using plasmids.

**K.D.** You mentioned you have a bank of plasmids.

**W.M.** We have a bank with ninety plasmids in total so far. Fifteen are usable for screening and identification purposes. Three could be employed for sure in Real-time PCR.

**K.D.** This is going quite fast! You did a very good job!

**W.M.** Yes, but we have very unstable means to develop this further and for that reason I am looking for companies to finance us. I do not know who is going to pay for all this! So perhaps we could maintain other stable activities such as cloning. You can clone amplicons and this can be useful in terms of validation of the method. They provide the method. We can provide the plasmid directly from what we have got.

**K.D.** Have you been able to find any company so far?

**W.M.** No... I do not think that companies will ever develop the reference genes we are talking about, because, even if they could develop what they want, we are the ones producing the reference system and validating it.

**K.D.** I was just wondering whether they could support you in the beginning...

**W.M.** Frankly, I prefer to dispose of less money but not to have someone who can influence me on the choice of amplicons, in the cloning which have to strictly comply with the regulatory dossier. The companies do not have any of these dossiers. We only can check that the amplicons we are using are written in them. Afterwards, it will be up to the Commission to decide whether to make this information publicly available. In this case, yes of course, we will have to protect our rights, too! This is public money, public funding so we are forced to publish but once the plasmids are available everybody could take them. Monsanto, for instance, could buy all of them and ask to be paid for them! So far there is no way to protect from these scenarios arising.

**K.D.** This is not easy.

**W.M.** You see, traditionally, in practice, the companies have the power to control the RMs and this may lead to clashes with the CAs in the future. What will be their role? This should be clearly stated. Is this a political decision or a matter of quality of the

procedure? If we intend to frame the use of plasmids inside the activities of accredited labs belonging to the network this should be made clear.

**K.D.** This is tricky. Who will take this responsibility? In my opinion it is part of the Commission's duties to support and defend the role of ENGL.

**R.S.** **How do you imagine the future of ENGL?**

**W.M.** So, where are we going now? I think our top priority is to deliver to the outside through our websites, through mails, attendance to conferences, scientific presentations and articles...

**K.D.** This is very important! Communication is very important! Not only among members but also with all persons who might be interested. We have to spread information outside the network. Websites might be very useful with this regard. They are a way to share experiences immediately. I would also like to repeat the experience of the Varna meeting we had in September. It would be nice to involve a wider number of representatives i.e. US, South America, China, Japan etc., but I can imagine it would take a lot of time to organise such an event! Concerning the short term, we will host the Inauguration Ceremony of ENGL for PECO countries next year. We are very proud that Prague has been chosen as the venue of this important event and we will do our utmost to make it a success!

**R.S.** **Some adjectives to define the ENGL?**

**K.D.** Belonging to the network as full members will be very useful for us and will give us a lot of opportunities to improve our daily work. We would very much appreciate becoming members of the Steering Committee, if possible, in the future and would enable us to transfer knowledge and experience to our countries. For example, so far only one soybean from Monsanto has been authorised for placing on the market but cannot be grown. I do hope this situation will improve after our full accession to the EU.

**W.M.** One thought, if you look at the financing system of the Commission in relation to RTD, minimal resources have been allocated to us. A major part is allocated to the academies and industries. Nothing for us. Academies are usually involved in basic research, development of new technologies and their transfer to industries, which diversify their products accordingly. Whereas all we are doing is completely different. We do not have the funding. The Commission does not seem to take us into



*William Moens during his speech at the Inauguration Ceremony of the ENGL in Brussels on 4<sup>th</sup> December 2002.  
From left to right: European Commissioner Philippe Busquin, Kurt Van den Berghe (Commissioner's Office),  
Mr Moens and H J Buhk (Rki)*

account. The truth is that we have serious scientific problems upstream and concerning ENGL, there is no money for this project. This must be the responsibility of the Member States. This is not subsidiarity. There are EU scientific problems and they should be harmonised at EU level first and then at a local level. This is enforcement but there is also an intermediate step: which is ENGL!

**K.D.** *(She talks about the KeLDA project).* The project is stopping because there is no one to analyse the samples, which is peculiar because the project could be useful and spread worldwide.

**W.M.** CRL and ENGL could also play a role in terms of connection between Member States and scientific labs, accreditation, quality management, certification, referencing, proficiency testing, validation etc, not only for control activities. This is missing at EU level. We will never manage to keep the ENGL alive if there is no money to finance training, workshops, scientific research. (Here he finishes talking about microarrays and the huge investment this technology may require in terms of hardware and software).

*ENGL is an important forum for me to participate in discussions on GMO issues. It is important for me to participate in the Validation group and the Kelda Project with the aim to streamline my own laboratory. The discussions are always fruitful.*

Peter Lübeck, Denmark

*The ENGL is a mixed top-team and I hope that the network is able to stay on the ball, because the costs of reaction are always higher than investments in action.*

Rupert Hochegger, Austria

*The participation in ENGL meetings has been extremely useful for introducing*

*GMO testing in Estonia. It has also given important personal contacts with colleagues from other labs..*

Merike Kelve, Estonia

*The experience has been positive. The ENGL allows to exchange scientific information, to develop regulation provisions, to discuss technical or practical problems and to be updated on different events regarding GMOs.*

*It also helps a lot to have personal contacts with people in charge of GMO in other Countries and institutions.*

Almudena Rodríguez Sánchez-Beato, Belgium

*It is a network of scientists concerned by the sampling, detection, identification, quantitation of GMO seeds, commodities and ingredients from the field to the dish and backwards. ENGL is the interface between the scientists of the Commission and those from the enforcement and associated laboratories. ENGL laboratories will apply the CRL validated methods to the real market and disseminate their results.*

William Moens, Belgium

# Personal Experience



1

What is ENGL for your country?

2

What is ENGL for your professional life?

3

What is your personal perception/experience with ENGL?





# Austria

## and the European Network of GMO Laboratories

The ENGL has become a very important platform for exchanging information between authorities, scientists and other stakeholders in the last few years. This development was mainly due to the energy Guy Van den Eede and his team at the JRC put into the Network but also due to the fact that it offers the unique possibility to meet people from all over Europe (the enlarged one!) with the same interest — analysis and research in the field of GMOs — on a regular basis and discuss with them. I was asked, and it is a great honor for me to follow this request, to write a few lines on my personal point of view regarding the ENGL.

### 1

As Austria is a small country, situated at the border of the old EU and right in the middle of the enlarged Europe, having contacts to Western, Central and East European countries is very important. This is not only true for the GMO business but for all areas. At least in the field of GMOs the ENGL provides a unique information network, enabling the members to establish contacts and developing common projects.

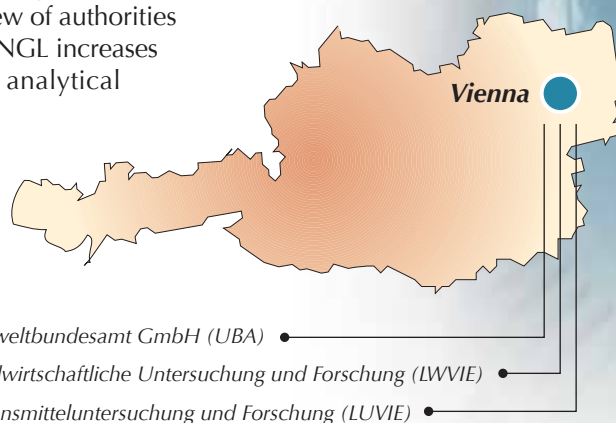
The number of GMO-laboratories in Austria is quite small, and though they are experienced in carrying out analyses and are maintaining high level quality assurance systems, their research capacity is limited. Another problem we are facing is, that though there is an intense exchange between the laboratories, it is not that easy to reach a “critical mass” under this circumstances. For control laboratories in Austria therefore it is absolutely necessary to establish co-operation with laboratories from outside the country. The ENGL has become a major source for analytical methods but also for background information exchanged during the meetings or via the bulletin board. This information and co-operation does not only facilitate the control of GMOs for the laboratories but also saves a lot of money for the authorities which otherwise has to be spent in developing and validating analytical methods.

### 2

Becoming a member of the ENGL was a major step for my professional life and the recognition of the Umweltbundesamt as an expert institution in the area of GMO-analysis. Just one example: As mentioned above Austria has a strong relationship with some of the enlargement countries. My institute is carrying out Twinning projects in the framework of the EU PHARE program with the aim of assisting authorities in some of the enlargement countries in setting up biosafety monitoring systems. Being a member of the ENGL (and the Steering Committee) was one important factor in getting this projects, and is always a great help during negotiations.

But not only for the application for projects having the ENGL “in the back” has become a major point. I recognized, that the expertise of the Umweltbundesamt and myself has been upgraded in the view of authorities but also for NGOs and other stakeholders. Referring to the ENGL increases the strength of arguments and the position in discussing analytical possibilities and challenges.

To be member of the ENGL means for me to have access to interesting projects, meeting interesting people inside and outside the Network, and having the chance to discuss my ideas with a number of the best experts in Europe.



### 3

When I'm thinking about the ENGL and the past few years this network has been existing, many positive pictures come into my mind. It is hard to pick the right or "most representative" ones. As we have recognized during our work within the ENGL sampling is one of the mayor challenges in the GMO business. To cover the many and very heterogeneous aspects of the ENGL a large number of "samples" has to be taken from the last years experience — and that would certainly be beyond the scope of this report. Therefore I'll try to pick just a few thought's and events, hoping they'll give some impression on my very personal view of the ENGL.

The ENGL is some kind of big family. Though the involved laboratories are in various stages of development (like children of different age), I have the feeling that knowing each other for a long time, working together, and meeting at least twice year has brought all the people together. The common interest, a professional respect but also the will to assist each other in solving problems in the laboratory are the key to the success

of the ENGL. Besides the professional level there always questions asked during the breaks like "How are your kids?", "Have you already moved to your new house?" or "Did you enjoy the skiing?". I think this shows, that there is also a personal interest that keeps this group together.

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*In my opinion within the ENGL we have a solid structure and a lot of people who want to keep the Network alive*

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The ENGL is a real network. Of course all the members are experts and are highly qualified in their field of work.

But a group of experts, even if they are coming from all over Europe, is still not a "Network". What is needed to build up a network? First of all there has to be one to keep the net together. Than there are the people, who build up the net. There has to be common goal. That's the structure. But this structure has to be filled with life. In my opinion within the ENGL we have a solid structure and a lot of people who give inputs, discussing their ideas, developing projects – at short: who want to keep the Network alive. We have developed a "corporate identity". And therefore the ENGL lives.

Last not least I want to tell a story which happened during the conference about "The ENGL in an Enlarged Europe" held in Varna, Bulgaria. After the conference dinner — as usually — a lot of discussion was going on about projects, GMOs in general, and the position of the ENGL. I was lucky to be at a table with our chairman, some other people from the network and two colleagues from Cyprus. Suddenly one of these, in order to draw a picture on the position of the ENGL in the enlargement countries, said "You know what? The JRC and the ENGL are the Mekka for the GMO laboratories!". Our chairman was shocked for a moment. Than he started to argue: to say such a thing overestimates the importance and puts much to much responsibilities and pressure on the ENGL and on the JRC. We all (!) tried to convince him, that, besides "Mekka" may be a little bit to religious, the statement was absolutely correct. I remember that we discussed on this topic for hours and went to bed long after midnight. To get up the next day was terrible. But for me, and I think for most of us sitting together this night, it was very a very satisfying and optimistic discussion: to hear all people offering their support to the JRC, to hear examples of other enlargement countries, and to hear so many arguments, why the ENGL is so successful and important. And that's what it is: THE centre of excellence for research, method development and validation for GMO analysis in Europe.

**Andreas Heissenberger**  
Umweltbundesamt (UBA)  
Austria

# Belgium

## and the European Network of GMO Laboratories

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ENGL is still a matter of careful interests and hopes in Belgium. But I do assist to a growing curiosity of the big heads since the first ENGL achievements are starting to impact at several decisional levels of many EU members.

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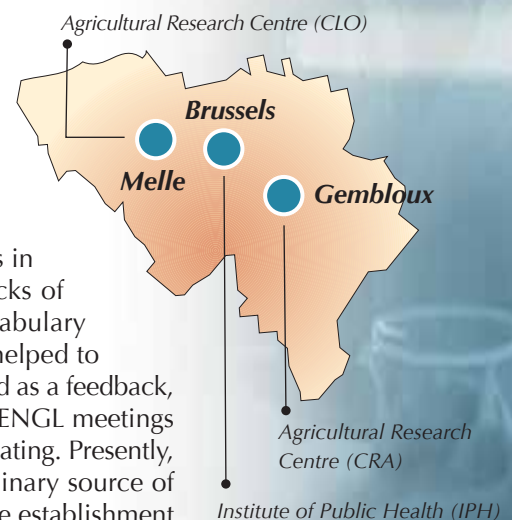
Since 1999, ENGL is growingly a part of my professional life. As member of the steering committee, I have to relay the questions from the Belgian authorities and associated laboratories and those of our partners. I also have to adapt progressively my laboratory framework to the norms and to the technologies harmonized in ENGL fora.

3

I was lucky to participate to the very early 1999 discussions that initiated the ENGL project. Since, I never stopped to commit myself in this project.

to Working group of the CODEX Alimentarius and of CEN/ISO aiming at defining normative guidelines for the detection and quantification of GMOs in foodstuff. Berlin-DIN was certainly the place where the future ENGL bricks of the “modular approach” have been designed: common concepts and vocabulary has been conceived by people from allover the world. This tremendously helped to provide the network with a common communication interface. Afterwards and as a feedback, the ENGL work has improved the achievements at the CEN and ISO levels. ENGL meetings have become a place to test ideas and methods. This is very exiting and stimulating. Presently,

ENGL is also a multidisciplinary source of scientific consultancy for the establishment of the Community Reference Laboratory defined by the new GMO regulations. ENGL work will not be finished with the institution of the CRL. At the contrary, the CRL will very soon starts to establish the scientific and methodological references for hundreds



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*ENGL meetings have become a place  
to test ideas and methods.  
This is very exiting and stimulating*

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laboratories of the enlarged EU. Exploring the applicability of reference methods is certainly the big strength of the network: a huge amount of research in food and environmental technologies is consequently in front of the ENGL laboratories.

I'm pretty confident that ENGL and the forthcoming CRL are going to build a new framework useful for the consumers, the industry and the authorities allover the world. CRL-ENGL is no less than a new major reference for a more predictable market. ENGL is apparently perceived as such since it becomes critized in the scientific literature, a very good signal that it is taken seriously.

My hope is that our colleagues and friends outside the EU will join the game and help to improve the technologies and strategies to scale down the overheads and uncertainties linked to any new growing framework .

In the meantime, I enjoy not only the European and pioneering atmosphere of ENGL but also the privilege to work with highly motivated people.

**William Moens**  
Institute of Public Health  
Belgium

## Cyprus and the European Network of GMO Laboratories

On the 4<sup>th</sup> of December 2003, the European Network of GMO Laboratories (ENGL) was consolidated following the Inauguration Ceremony and the official signing of the agreement. Commissioner Philippe Busquin, Director General Barry Mc Sweeney, IHCP Director Keens Van Leeuwen and representatives of 44 European Laboratories were present. Along with the Inauguration Ceremony, a stakeholder's conference as well as the first official ENGL plenary meeting took place with 74 participants. Cyprus was present in all three meetings as an observer.

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*Cyprus became full member of ENGL in April 2004. Even though at that stage it was only an observer it has always received full benefits and help, as it was a full ENGL member*

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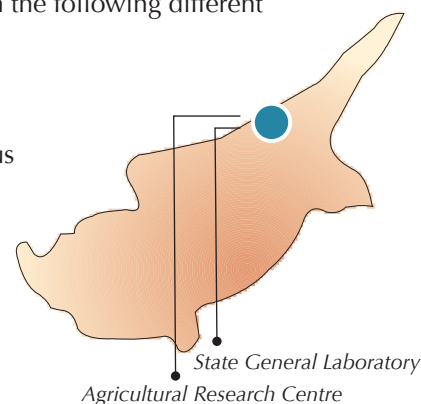
ENGL has been set up to create a forum for EU and EEA to collaborate on sampling, detection, identification and quantification of GMOs. Through the three plenary meetings, the steering committee meetings, two GMO training courses and a stakeholders' meeting for an Enlarged Europe during the last one year of its life, ENGL has achieved its goals. The characteristic of every such meeting is the brainstorming taking place among experts. The results of every meeting are disseminated to all members and a vivid discussion

always follows via Internet. ENGL also assists new member countries such as Cyprus to set up and continuously develop the technical infrastructure necessary for the practical implementation of the body of EU law.

Cyprus became full member of ENGL in April 2004 along with the other nine new Member States. Even though at that stage Cyprus was only an observer, it has always received full benefits and help, as if it were a full ENGL member. The help that Cyprus receives to harmonize its approaches in the development, validation and implementation of analytical methods for the identification of GMOs is important. The assistance Cyprus received from ENGL during 2003 could be distinguished in the following different levels:

### Legislative Issues

In September 2003, the House of Representatives of the Republic of Cyprus passed the Directive 2001/18/EC into a national law. I was one of the experts on GMO issues along with two other colleagues who were called by the House of Representatives Environment Committee to assist in tackling the scientific aspects of the legislation. During the long discussions our team remained in constant communication with different members of ENGL who have experience on legislative issues in order to obtain feedback on relevant aspects arising along the way. I should point out that the assistance we received from the ENGL experts was very useful.



### GMO Training

A colleague from the State General Laboratory (Ministry of Health) and my self attended a one-week intensive training course on GMO detection methods – “The analysis of food samples for the presence of Genetically Modified Organisms” held at the Joint Research Centre in Ispra, Italy. The course was offered by the Biotechnology and GMOs Unit (Institute for Health & Consumer Protection, Joint Research Centre, European Commission) in collaboration with the World Health Organization (Regional Office for Europe). During the course we were acquainted with various laboratory techniques and methods and we attended several scientific lectures delivered by experts. Overall I rate the training course as excellent.

At the last plenary ENGL meeting, it was agreed that the next extended training course on the analysis of food samples for the presence of Genetically Modified Organisms will take place in Cyprus, next September.



### **Molecular Biology Laboratory (MBL)**

The Ministry of Agriculture, Natural Resources and Environment has assigned the MBL at the Agricultural Research Institute as the Competent Authority for technical and scientific issues regarding Directive 2001/18/EC.

As the leader of MBL, I undertook the task of preparing the Laboratory for conducting GMO analyses. This preparation included the following steps:

1. Developing infrastructure
2. Transfer of Know-how
3. Instrumentation
4. Laboratory accreditation

The close collaboration and support from the experts of ENGL guarantees the outcome of this major and difficult task.

As an epilogue I would like to state that it is a privilege to be a member of ENGL as, during the last year, I had the opportunity to meet a group of wonderful people and excellent scientists. I was informed on all the latest scientific advancements regarding GMOs as well as being a partner in an FP-6 project submitted by ENGL.

**Ioannis M. Ioannides**

Agricultural Research Institute  
Cyprus

# Norway

## and the European Network of GMO Laboratories

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Norway is not a member of the European Union, although we have close collaboration with the EU through the EEA (regulating legal and trade issues), Schengen agreement (regulating the free movement of people between countries in Europe) and ERA (Research framework programmes like FP6). Through the EEA there is extensive adoption of EU legislation and trade agreements and rules in Norway. This is frequently described as a B-membership in the EU, because we have no direct influence on the decisions taken by the EU while we have to implement the results of many of these decisions. The indirect influence coming from the participation in bodies like the ENGL that are important suppliers of background information for decision makers is therefore particularly important for my country. Here we have the opportunity to present our own ideas and views, exchange experience

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*We have the opportunity to present our own ideas and views, exchange experience and know-how, listen to and participate in the discussions without restrictions*

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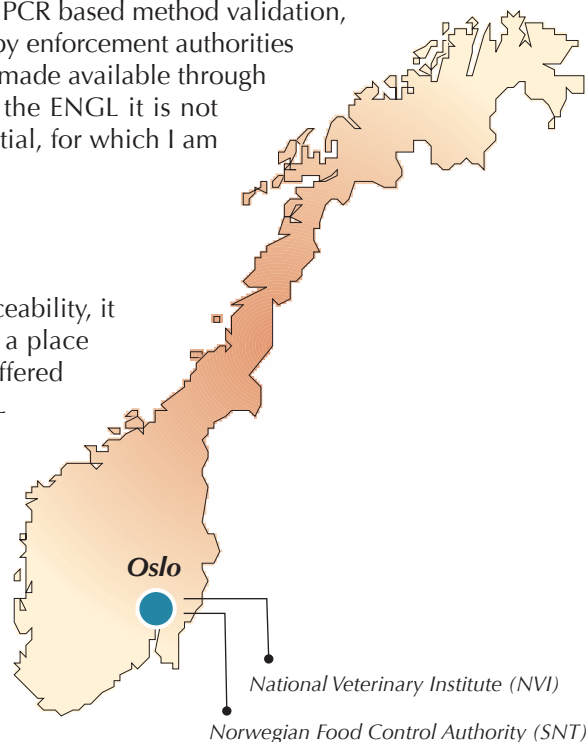
and know-how, and listen to and participate in the discussions without restrictions. In the specific area of GMO traceability, I believe our participation in ENGL offers the best possible facility to keep ourselves updated, to provide scientifically based background information to decision makers, and to establish a dialogue with the EU with particular relevance to GMO legislation.

2

Through the ENGL I have established, reinforced and continued scientific collaboration with some of the greatest experts in the world regarding GMO traceability and detection methods. The level of the scientific discussions is often in the international forefront, and I believe some of the most influential ideas relevant to GMO traceability legislation, GMO detection methods, PCR based method validation, GMO reference materials and implementation of GMO legislation by enforcement authorities have been developed and/or shaped by the scientific environment made available through the ENGL. As an active participant in most of the discussions in the ENGL it is not surprising that this leaves me with the feeling of being truly influential, for which I am very grateful.

3

While ENGL is a mix of experts on different aspects of GMO traceability, it is my impression that the vast majority of delegates feel that this is a place where the learning curve is steep while at the same time room is offered for asking simple questions and receiving adequate answers. The ENGL offers a very friendly environment, while at the same time keeping focus on the business. Time spent with ENGL is rarely non-productive time, and I always look forward to taking up the discussions with my colleagues and what have often become good friends as well. Personally, I believe that I have contributed one of the most influential ideas to the international traceability debate through the ENGL by strongly promoting the modular approach for method validation and application. This approach as it is promoted via the ENGL is a trueborn child of the creative scientific environment offered by the ENGL, and would probably never have matured without the ENGL.



**Arne Holst Jensen**

National Veterinary Institute  
Norway

# Slovenia

## and the European Network of GMO Laboratories

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Slovenia is a small country, intensively establishing its biosafety framework. The detection of GMOs is one of the important issues in this system, supporting the regulations on labelling and traceability, as well as environmentally related concerns on GMOs. Since Slovenia is a preaccession country, charring the experiences and ideas with European Union members is a very valuable possibility offered by ENGL. During the last year also some of the EU members of ENGL came in Slovenia as guests in the workshops organized by National institute of Biology together with the Ministry of Environment, Spatial planning and Energy in

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the frame of UNEP-GEF project. Their input and experiences shared with different stakeholders were very important also as a support for decision making in establishing the whole system on GMO traceability in Slovenia.

2

The ENGL network is a community of different profiles of people, working on routine analysis as well as basic research on GMOs. The close interaction with them means exchange of practical experiences in official control of GMO in different countries, methods used, interpretation of the results, decision making experiences. On the other hand there is a possibility for joining basic research efforts and ideas, leading at the end to the establishment of more precise and cost effective methods for detection of GMOs which will again be used further on in official control in the whole food chain from the field to the store shelves. For me this a rear opportunity to really work in an expert group where the critical mass of knowledge is achieved, which makes the group really effective and productive. So the cooperation in ENGL means a great enrichment of my professional life.



3

As the Head of ENGL Guy Van den Eede said on one of these nice evenings after the whole day meeting, that we are all one big family, I must say that I completely agree with him, that it is not only profession and GMOs that we are sharing, but also the friendship among all members. His efficient leadership, strong and focus ideas about the network, supported by experienced members of the group, as well as consent from all members that he always try to achieve are adding a lot to this filling. So my perception of the ENGL is that this network is one of the best experiences I had in my professional life.

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